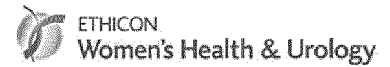


EXHIBIT B-5

CAPA #130022 – Repetition of NCR for particles**Adaptiv change project # to update when/if necessary****Team Meeting Minute****Mar 08, 2013**

09.04.13
JOURNOS Vincent
[Signature]
USD

Attendance:

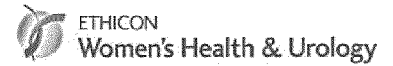
Team Member	Function	Attendance
Angélique Lou	Team Leader EWHU	X
Sandra Chamouton	Quality Technician	X
Severine Timoner Fortin	Procurement	X
Cornelius Felgenhauer	Procurement	
Carmel Lowe	CAPA site Leader	
Nicolas Couthion	Laboratory Analyst	X
Sarala Padala	Microbiology & Sterilization Mgr.	
Margaret Bolton	QA Engineering Lead	X
Jody Lodge	Manufacturing Manager	X
Atimad El Fettouhi	QA Operations Leader	

Discussion: PPT PRESENTATION**Root cause analysis :**

- Presentation of context
- Realization of root cause analysis
 - o Interrogation during analysis :
 - Do we have proof that metallic particles come from positioning aid?
 - Arguments in favor of this hypothesis
 - o First particles found inside positioning aids original container
 - o Particles easily created by stretching positioning aids
 - o Particles found on products seems to be metallic and very similar
 - investigation in laboratory not necessary
 - Did our cleaning operation to remove particles on positioning aid implemented after first NCR worsened the situation by creating more particles?
 - Quick investigation shows that ultrasonic baths removed particles as intended but was inconclusive whether the hypothesis that ultrasonic bath created more particles. However Cleaning operation was added after the first NCR therefore it's not a potential root cause.
 - Is MediLine concerned too by these particles?
 - Question to ask to MediLine Séverine
 - Cornelia used same kind of temporary component, how is it managed?
 - Ask for information Séverine

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CAPA #130022 – Repetition of NCR for particles
Adaptiv change project # *to update when/if necessary*



- CONCLUSION:
 - o Causes will be written in document FM-0001222

Action plan definition:

- Start discussions of how to regularized the positioning aid system

Next Meeting: March 13th, 2013 – action plan discussion

VSD